STANDARD OPERATING PROCEDURE (SOP) ON ADVISING PATIENTS ON COMBINED ORAL CONTRACEPTIVE PILLS.

Department of Pharmacology
Faculty of Medicine
UWUSL 2026

1) Title

Advising patients on Combine Oral Contraceptive Pills (COCP)

2) Issued by

Department of Pharmacology
Faculty of Medicine
Uva Wellassa University

3) Purpose

To establish a standardized, evidence-informed procedure for assessing eligibility, initiating, counselling, supplying and monitoring combined oral contraceptive pills (COCPs), while promoting informed choice, contraceptive effectiveness and patient safety

4) Scope

This SOP applies to undergraduate medical students, lecturers, clinical supervisors and authorized healthcare professionals involved in teaching or providing COCP-related care. It is an educational and clinical practice guide. Students must not independently prescribe or supply COCPs; all clinical decisions must be made by an appropriately authorized clinician in accordance with current Ministry of Health/FHB policy and institutional procedures.

5) Definitions

Term	Definition
COCP / COC	An oral contraceptive containing an oestrogen (Ethinylestradiol.30 – 50 mcg) and a progestogen.(Levonorgestrel 100-150mcg)
Active / hormonal pill	A tablet containing contraceptive hormones.
Placebo / iron tablet	A non-hormonal tablet included in some packs; it does not provide contraceptive hormones.
Quick start	Starting COCP on a day other than the first 5 days of menstrual bleeding after pregnancy has been reasonably excluded; backup contraception is required.
MEC (Medical Eligibility Criteria) category 1–4	WHO categories: 1 = no restriction; 2 = advantages generally outweigh risks; 3 = risks usually outweigh advantages; 4 = unacceptable health risk.

6) Responsibilities

(6.1) Lecturer / Academic Staff

(6.1.1) Explain the pharmacology, formulations, indications, benefits, limitations, contraindications and adverse effects of COCPs.

(6.1.2) Demonstrate structured eligibility assessment, blood-pressure measurement, counselling and documentation using simulated or anonymized cases.

(6.1.3) Supervise students during clinical learning and correct unsafe prescribing or counselling.

(6.1.4) Emphasize informed choice, confidentiality, respectful communication and referral of clients with potential contraindications.

(6.2) Medical Students / Healthcare Professionals

(6.2.1) Obtain a relevant medical, reproductive, medication and family history and assess pregnancy possibility.

(6.2.2) Measure and document blood pressure before COCP initiation; assess other relevant risk factors.

(6.2.3) Use the current WHO Medical Eligibility Criteria (MEC), applicable FHB guidance and local protocols to determine suitability.

(6.2.4) Explain correct pack use, missed-pill actions, expected adverse effects, warning symptoms, STI prevention and follow-up.

(6.2.5) Document assessment, counselling, decision, supply and referral; maintain confidentiality.

(6.3) Prescriber / Clinical Supervisor

(6.3.1) Confirm medical eligibility and select an appropriate formulation after considering patient preference, clinical risks, interactions and availability.

(6.3.2) Manage complications, review interacting medicines and arrange referral when required.

(6.3.3) Ensure that local protocols and the current product information are followed.

7) Ethical and professional considerations

(7.1) Provide non-judgmental, person-centered counselling and respect the client's autonomous, informed choice.

(7.2) Maintain privacy and confidentiality; obtain consent before examination or sharing information.

(7.3) Do not make COCP use conditional on partner consent or marital status.

(7.4) Explain that COCPs do not protect against sexually transmitted infections (STIs), including HIV; condoms provide STI protection.

(7.5) Do not initiate COCP solely on the basis of a checklist if a concerning medical history or abnormal blood pressure requires clinical assessment.

(7.6) Do not delay urgent assessment or referral in a client with symptoms suggestive of venous thromboembolism, stroke or other serious complications

8) Prerequisites

(8.1) Private setting and informed agreement to discuss contraception.



(8.2) Relevant menstrual, obstetric and contraceptive history; date of last menstrual period and recent unprotected sexual intercourse.



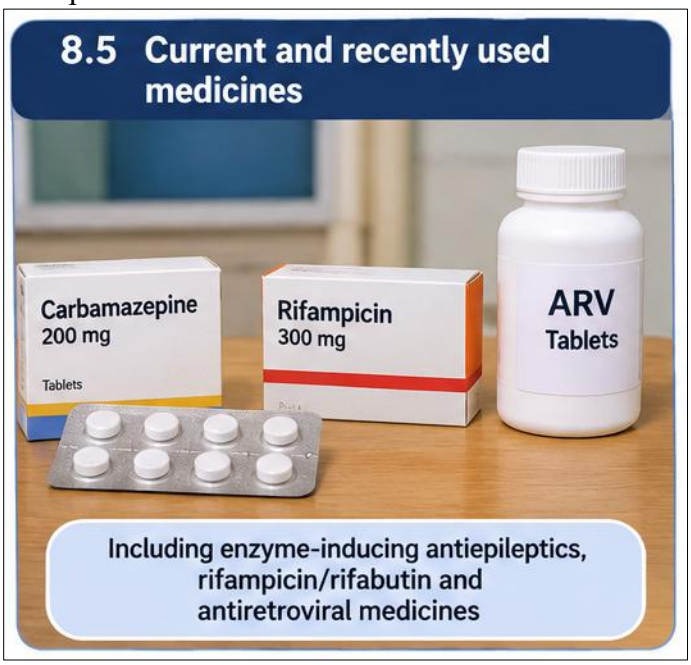
(8.3) Assessment to reasonably exclude pregnancy using history and pregnancy testing when indicated.



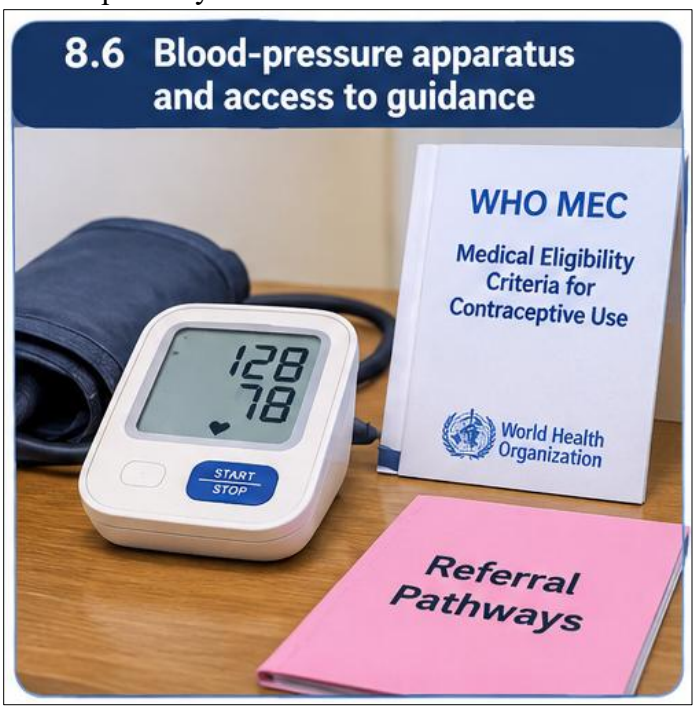
(8.4) Medical history including hypertension, migraine (especially aura), VTE/thrombophilia, stroke/ischaemic heart disease, smoking, diabetes/vascular complications, breast cancer, liver disease and planned surgery/immobilization.



(8.5) Current and recently used medicines, including enzyme-inducing antiepileptics, rifampicin and antiretroviral medicines.



(8.6) Blood-pressure apparatus and access to current WHO MEC/FHB guidance and local referral pathways.

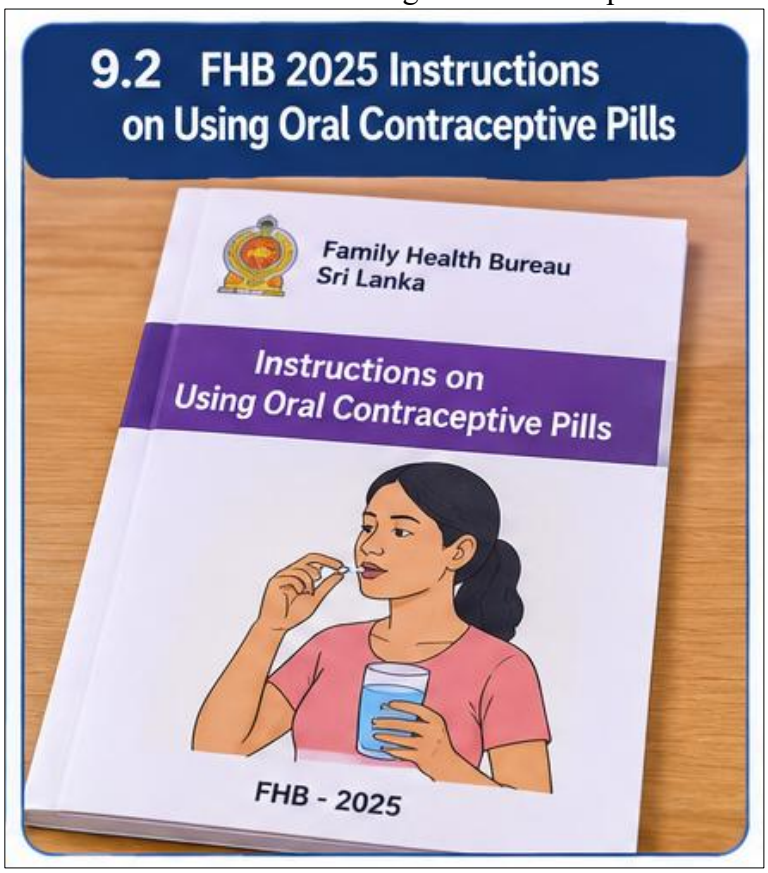


9) Materials / Information required

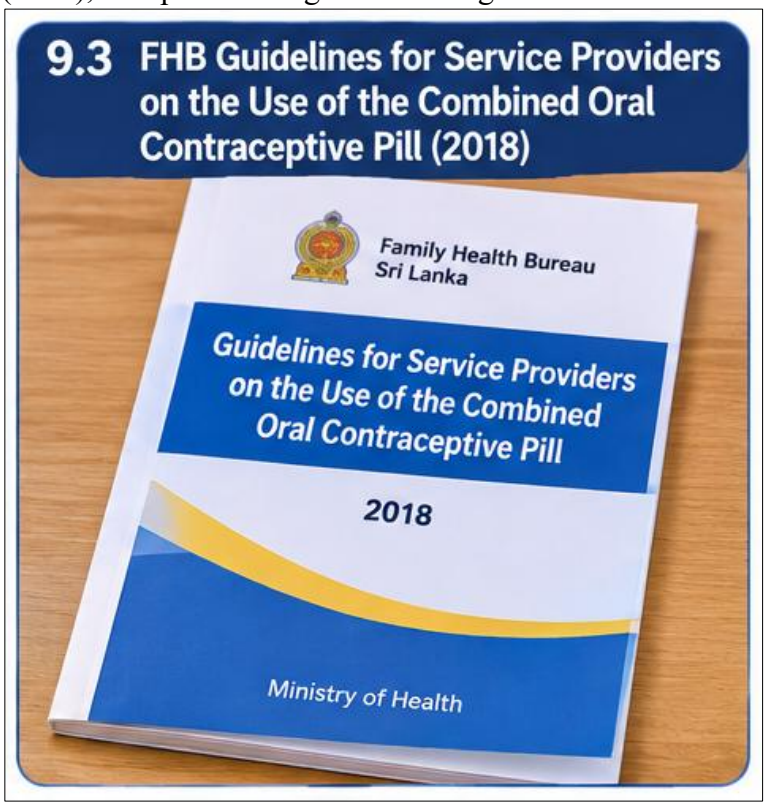
(9.1) COCP pack and the manufacturer's patient information leaflet.



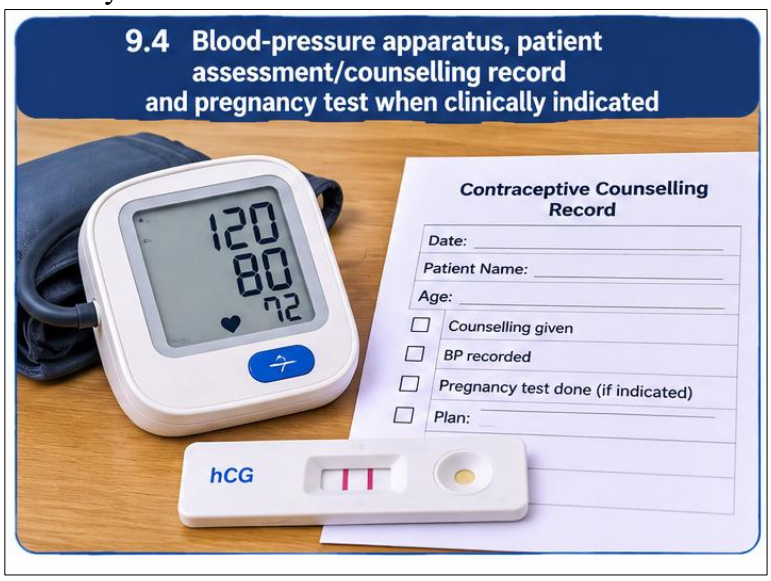
(9.2) FHB 2025 Instructions on Using Oral Contraceptive Pills.



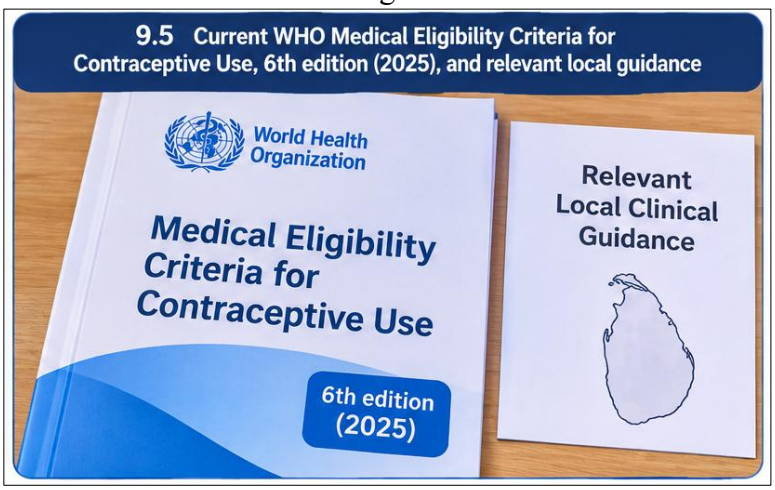
(9.3) FHB Guidelines for Service Providers on the Use of the Combined Oral Contraceptive Pill (2018), interpreted alongside current guidance.



(9.4) Blood-pressure apparatus, patient assessment/counselling record and pregnancy test when clinically indicated.



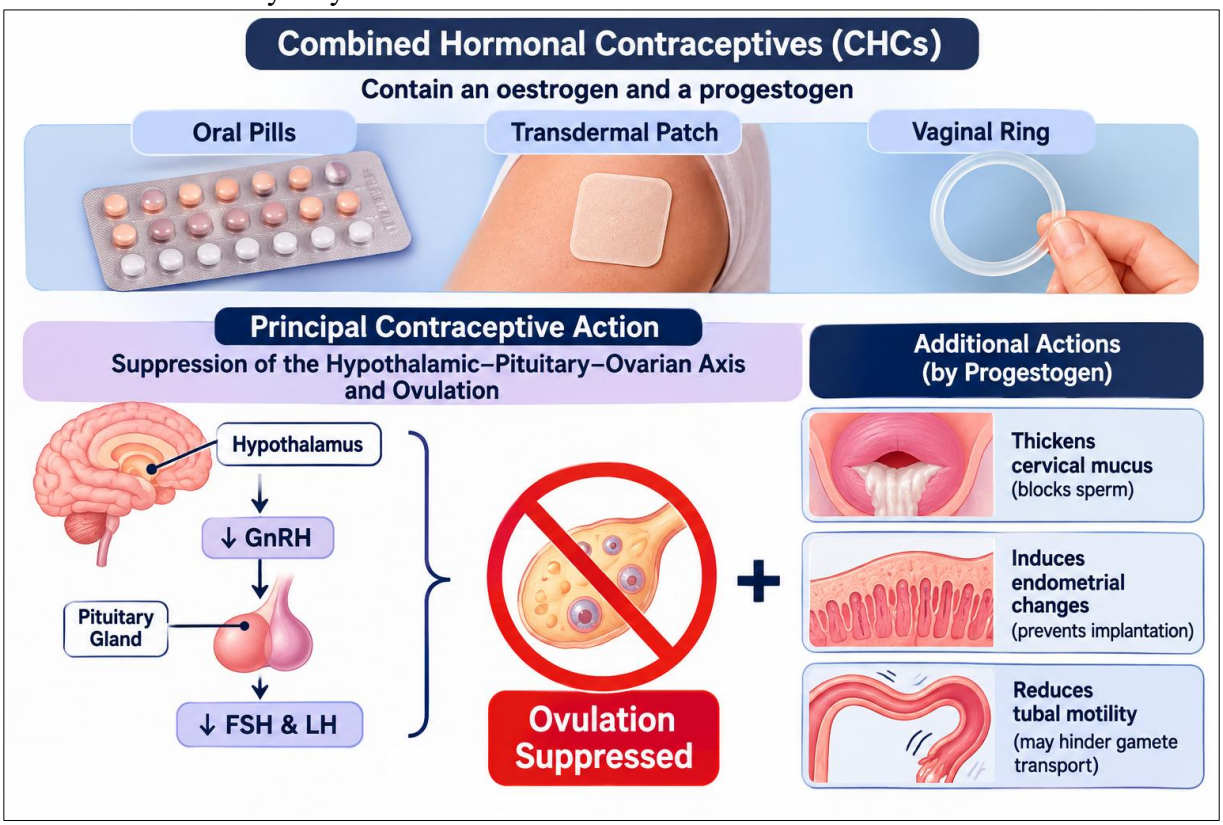
(9.5) Current WHO Medical Eligibility Criteria for Contraceptive Use, 6th edition (2025), and relevant local clinical guidance.



10) Pharmacology and Available packs

(10.1) Pharmacological basis

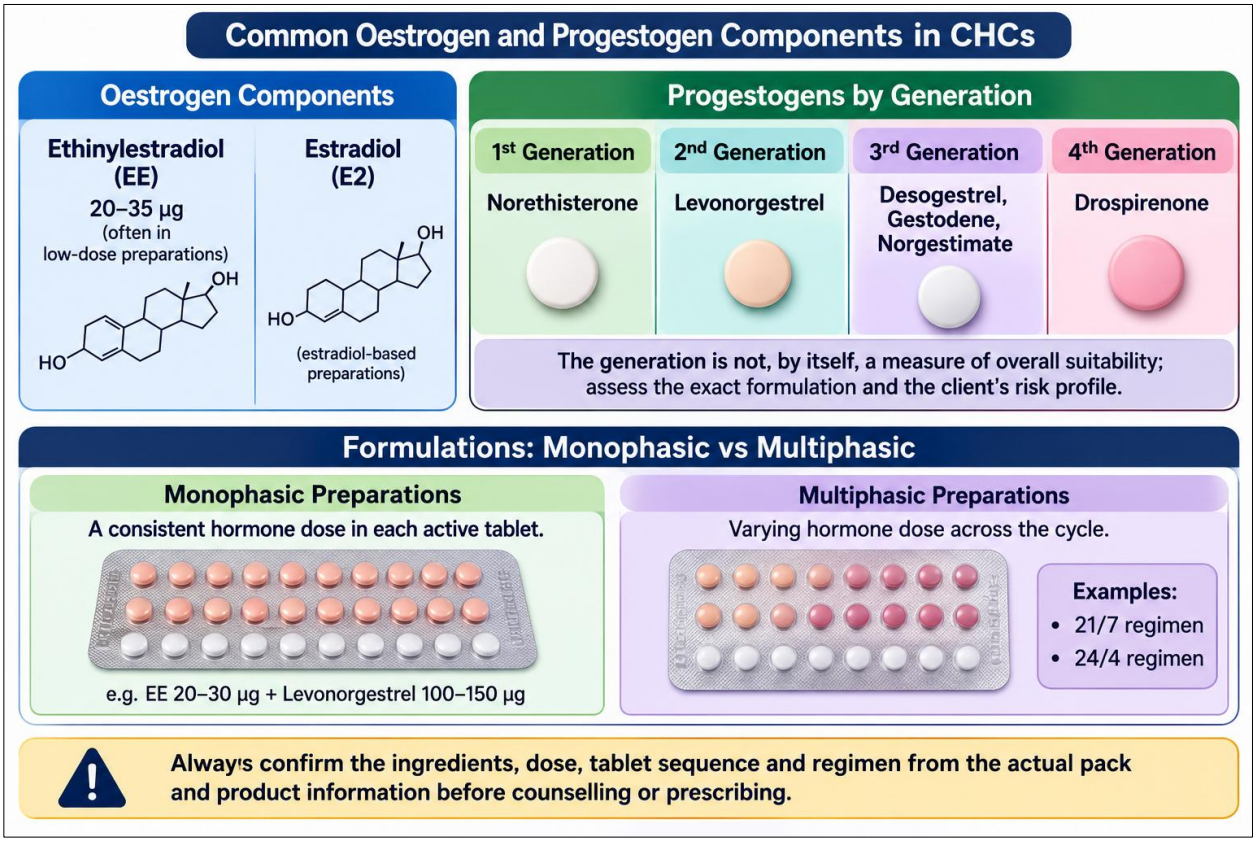
Combined hormonal contraceptives (CHCs) contain an oestrogen and a progestogen. They are available as oral pills, transdermal patches and vaginal rings. The principal contraceptive action is suppression of the hypothalamic–pituitary–ovarian axis and ovulation through inhibition of FSH and LH secretion. Progestogen also thickens cervical mucus and produces endometrial changes; reduced tubal motility may contribute.



Formulations differ in oestrogen dose and progestogen type; confirm the actual ingredients and regimen on the supplied product.

- Estrogens
    - Ethynyl estradiol 20-35ug
    - Estradiol content ; Theoretical reduced side effects
- Progestogens
    - Advantages
        - Convenient dosing intervals, more potent suppression of ovulation, prevents over-proliferation of endometrium
        - Newer generations have additional benefits of few anti-androgenic and glucocorticoid effects and anti-mineralocorticoid effects
    - Generations
        - First – **Norethisterone**
        - Second – **Levonorgestrel**
        - Third – **Desogestrel, Gestodene, Norgestimate**
        - Fourth – **Drospirenone**

Monophasic preparations contain a consistent hormone dose in each active tablet. Multiphasic preparations vary the dose across the cycle. Confirm the ingredients, dose, tablet sequence and regimen from the actual pack and product information before counselling or prescribing.



Examples of COCP Preparations Available in Sri Lanka – Brand and Dose

MITHURI	YASMIN	DIANE-35
		
Levonorgestrel 150 micrograms (0.15 mg) + Ethinylestradiol 30 micrograms (0.03 mg) per active tablet	Drospirenone 3 mg + Ethinylestradiol 30 micrograms (0.03 mg) per active tablet	Cyproterone acetate 2 mg + Ethinylestradiol 35 micrograms (0.035 mg) per tablet
21 active + 7 reminder/iron tablets (28-tablet pack)	21 active tablets (then 7 hormone-free days)	21 tablets (then 7-day tablet-free interval)

Clinical Caution

Diane-35 is primarily for androgen-dependent acne/hirsutism when other treatments are unsuitable or have failed; it is **not** a routine first-line contraceptive. Assess VTE risk and follow product guidance.

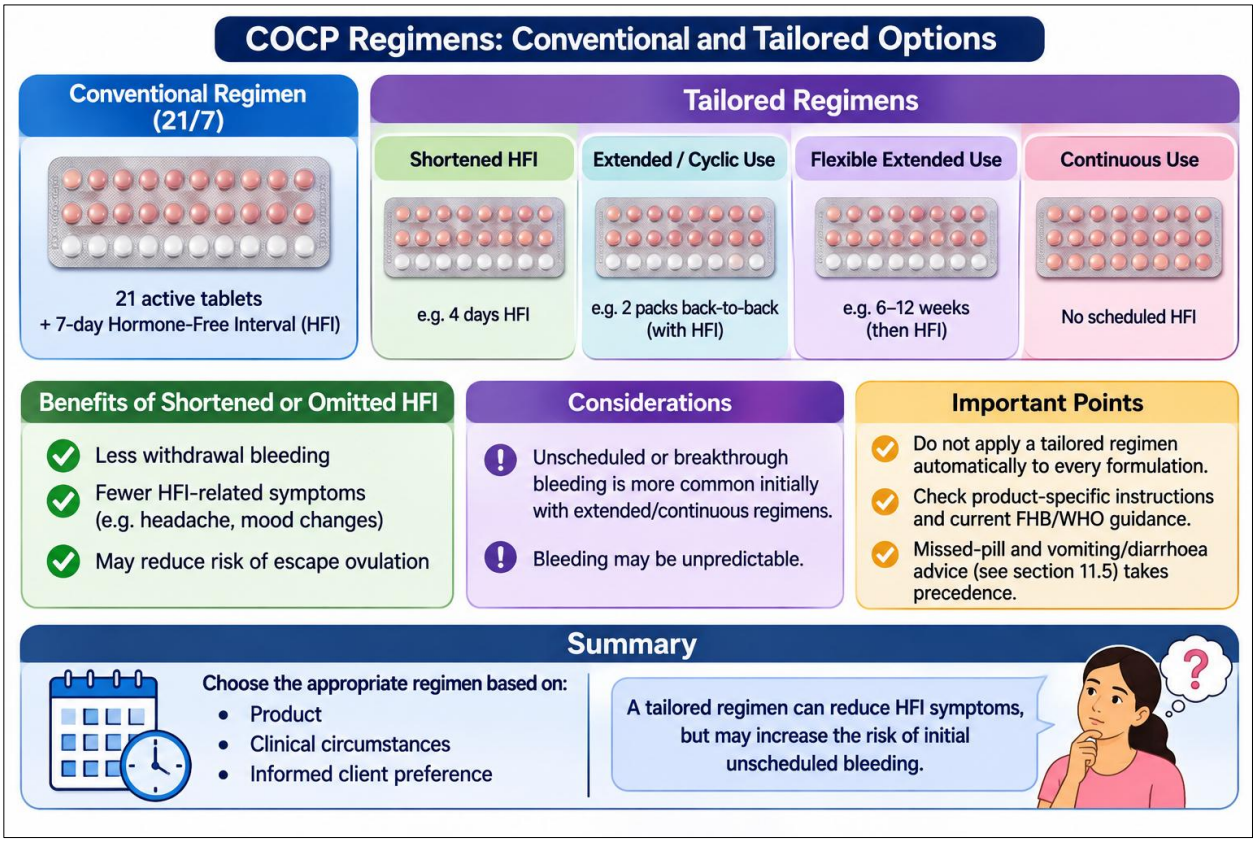
Brand availability and pack presentation can change. Verify the current Sri Lankan pack, NMRA status and product information before prescribing.

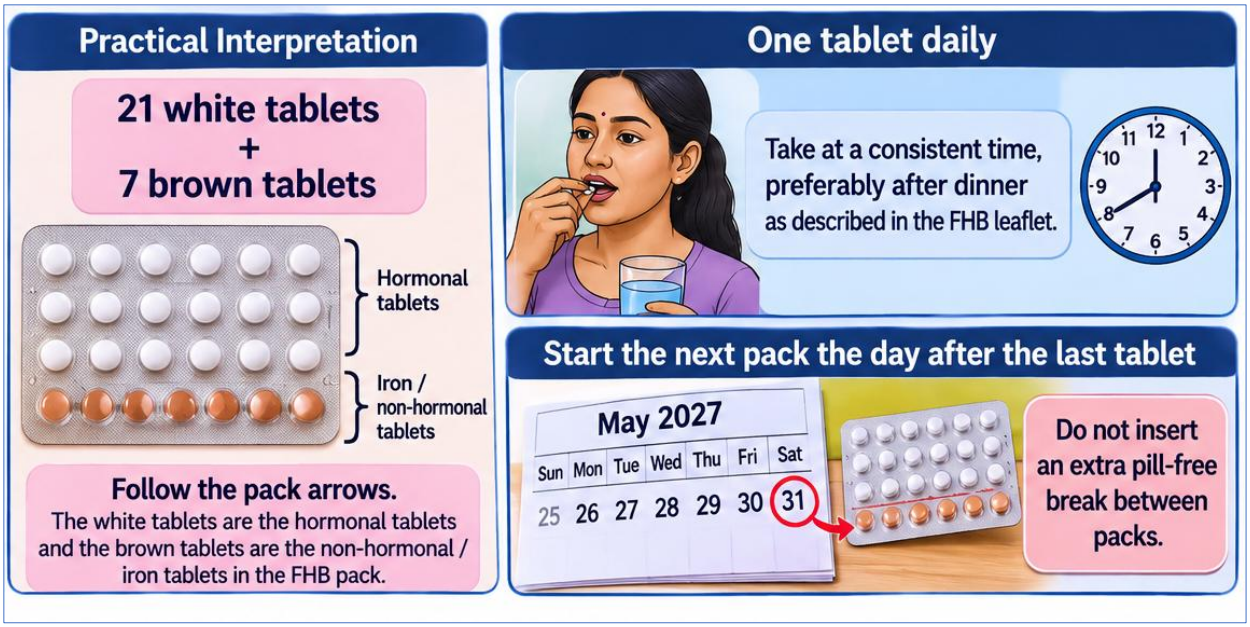


(10.2) Regimens and tailored use

A conventional regimen commonly uses 21 active tablets followed by a 7-day hormone-free interval (HFI), or an equivalent pack containing inactive tablets. Tailored regimens include a shortened HFI (for example, 4 days), extended/cyclic use, flexible extended use and continuous use without a scheduled HFI. The appropriate regimen depends on the product, clinical circumstances and informed client preference.

A shortened or omitted HFI can reduce withdrawal bleeding and symptoms associated with the HFI, such as headache and mood symptoms, and may reduce the opportunity for escape ovulation associated with an extended hormone-free interval. Explain that unscheduled or breakthrough bleeding is more common initially with extended or continuous regimens and may be unpredictable.

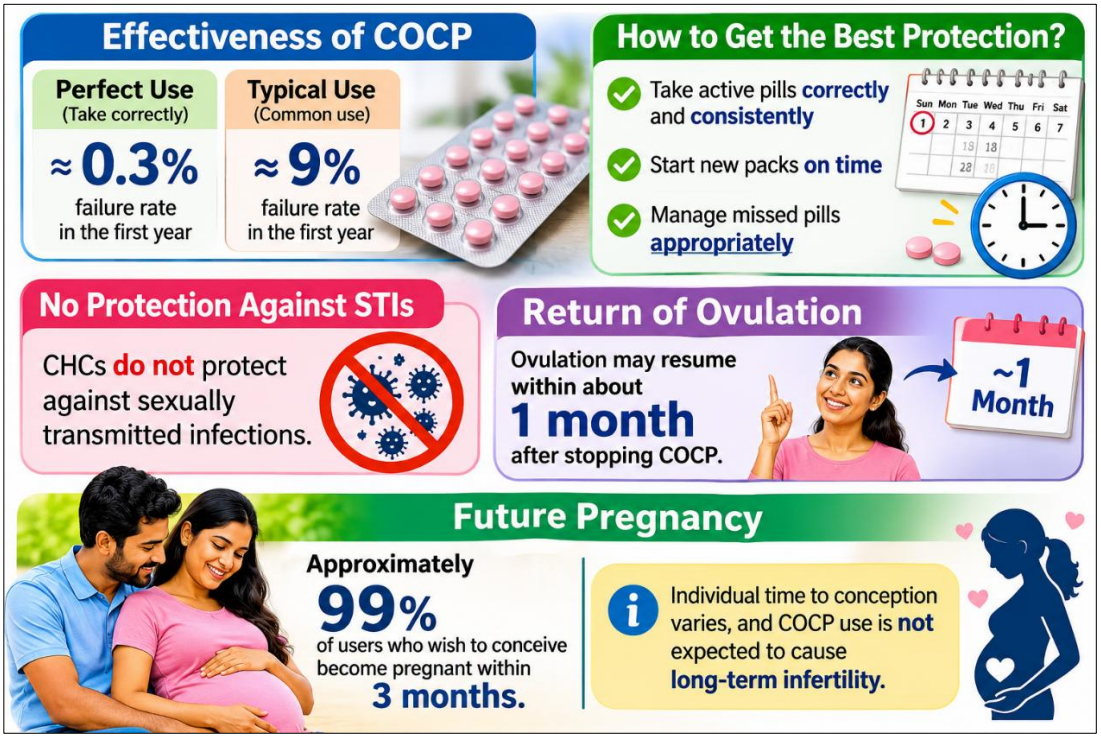




(10.3) Effectiveness and return to fertility

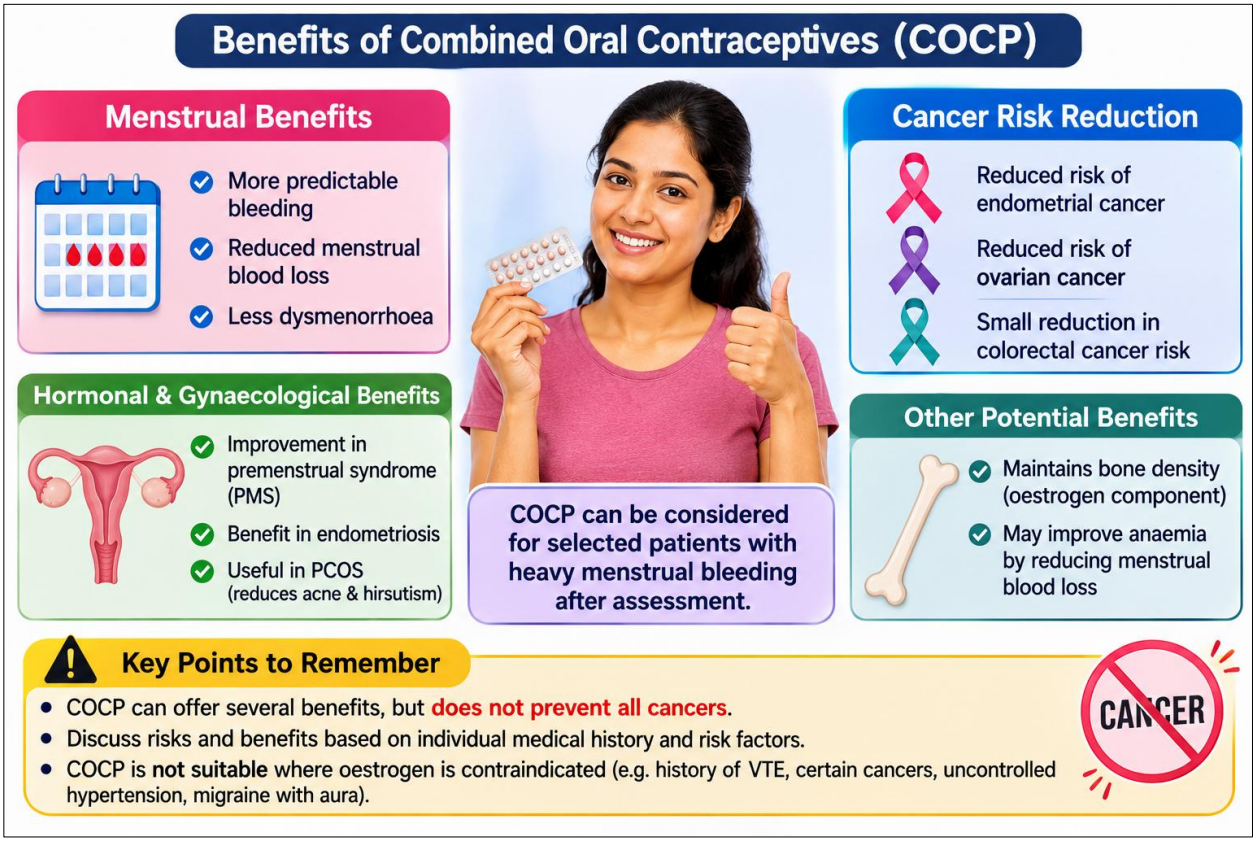
Approximate first-year failure rate of 0.3% with perfect use and 9% with typical use. Explain that effectiveness depends on taking active pills correctly and consistently, starting packs on time and managing missed pills appropriately. CHCs do not protect against sexually transmitted infections.

Ovulation may resume within about a month after stopping COCP. It reports that approximately 99% of users who wish to conceive become pregnant within three months; individual time to conception varies and COCP use is not expected to cause long-term infertility.



(10.4) Additional non-contraceptive benefits

Potential benefits include more predictable bleeding, reduced menstrual blood loss and dysmenorrhoea, and symptom improvement in premenstrual syndrome, endometriosis and polycystic ovary syndrome (including acne and hirsutism). COCP may be considered for selected patients with heavy menstrual bleeding after assessment. The note also describes reduced risks of endometrial and ovarian cancer with use, and a smaller reduction in colorectal cancer risk. Discuss benefits without implying that COCP prevents all cancers or is appropriate where oestrogen is contraindicated.



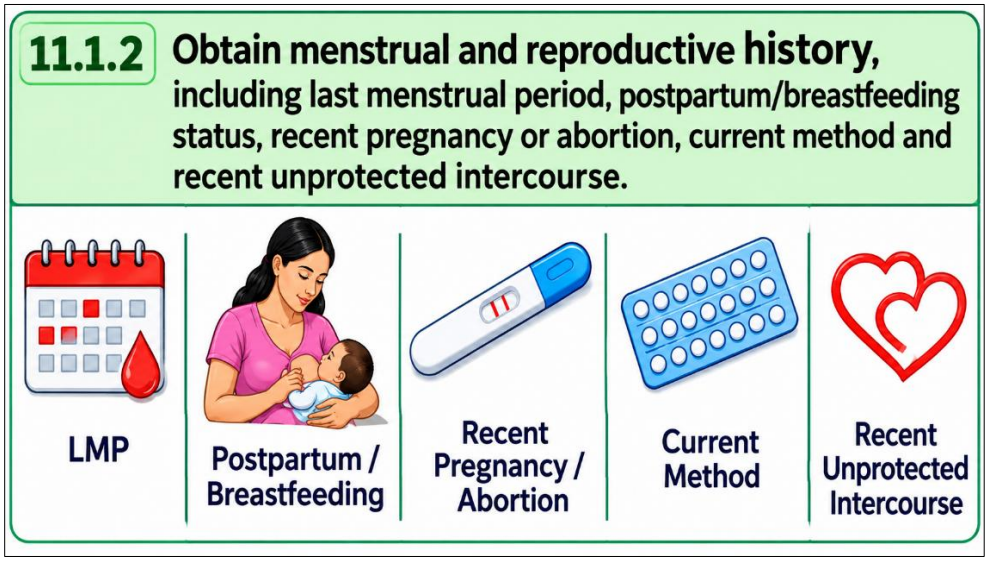
11) Procedure

(11.1) Initial consultation and assessment

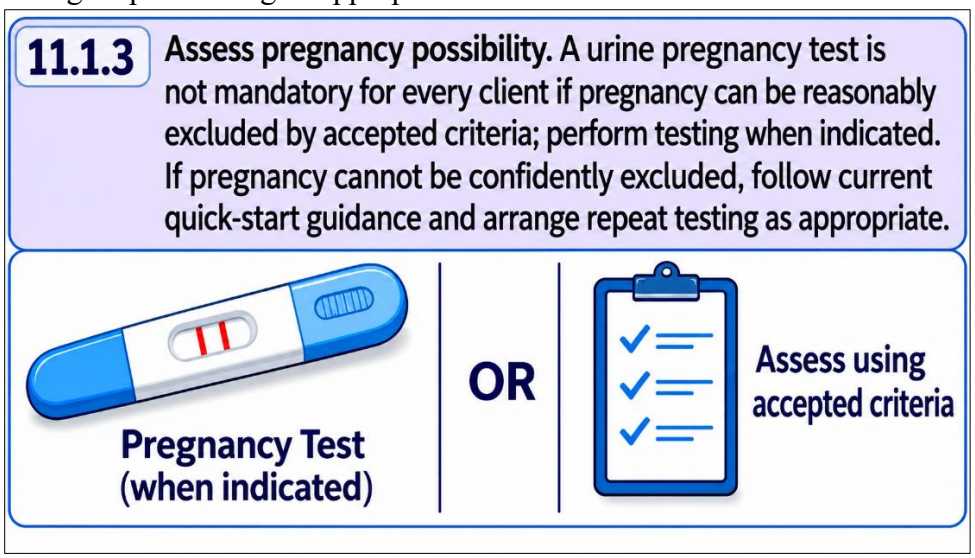
(11.1.1) Confirm the client's request, contraceptive goals, preferences and understanding. Discuss alternative methods without coercion.



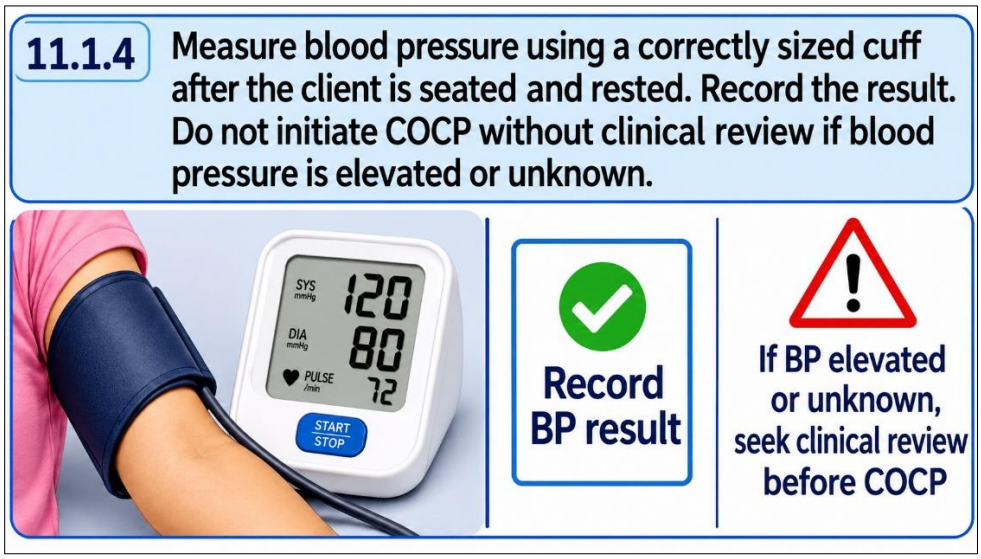
(11.1.2) Obtain menstrual and reproductive history, including last menstrual period, postpartum/breastfeeding status, recent pregnancy or abortion, current method and recent unprotected intercourse.



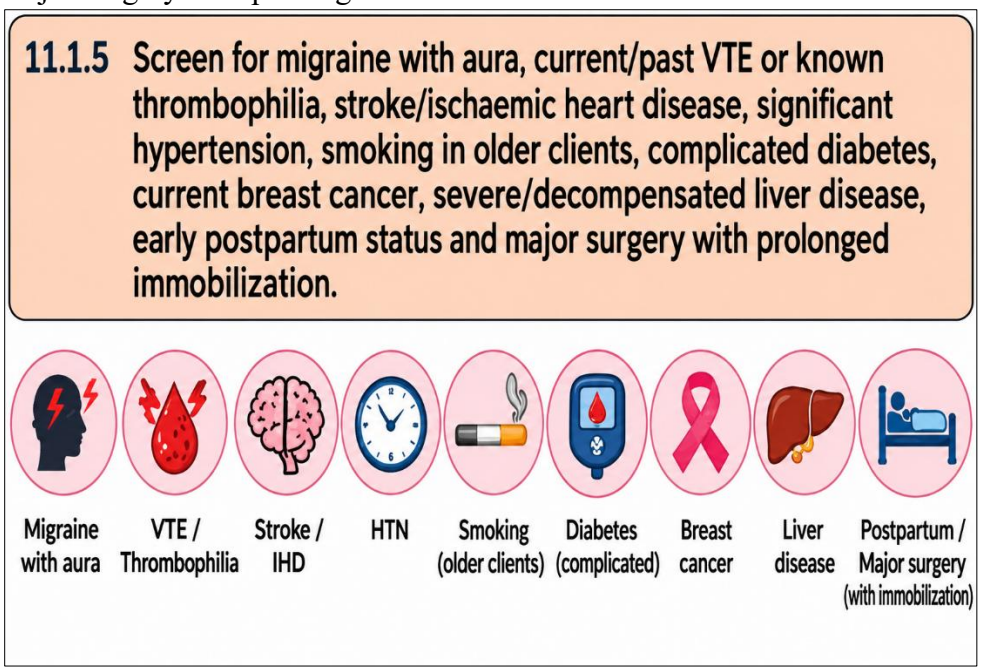
(11.1.3) Assess pregnancy possibility. A urine pregnancy test is not mandatory for every client if pregnancy can be reasonably excluded by accepted criteria; perform testing when indicated. If pregnancy cannot be confidently excluded, follow current quick-start guidance and arrange repeat testing as appropriate.



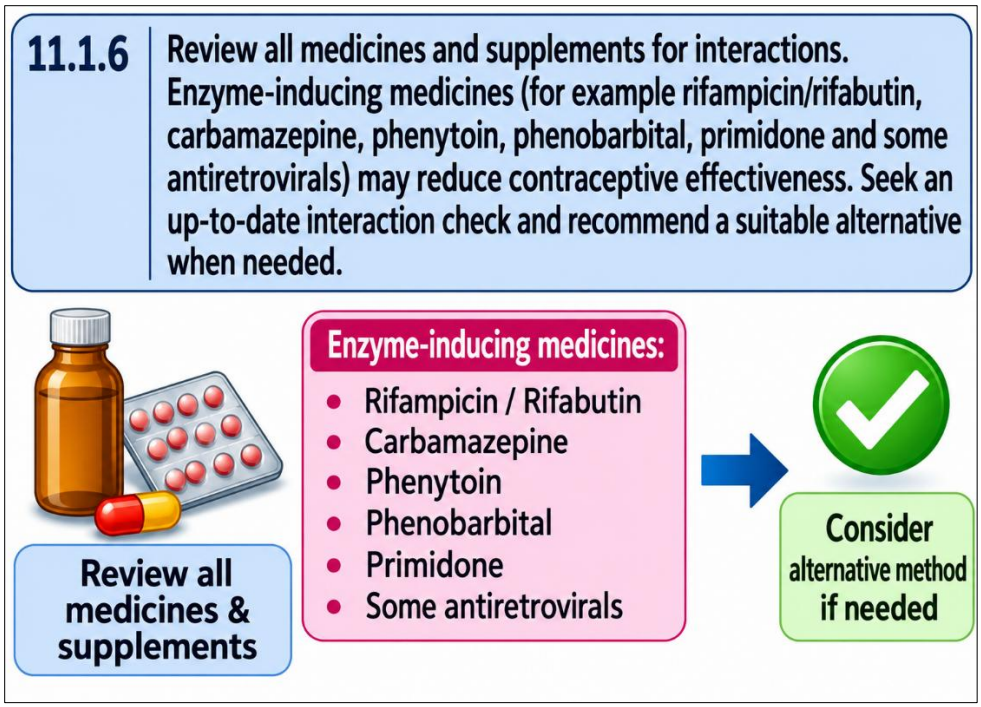
(11.1.4) Measure blood pressure using a correctly sized cuff after the client is seated and rested. Record the result. Do not initiate COCP without clinical review if blood pressure is elevated or unknown.



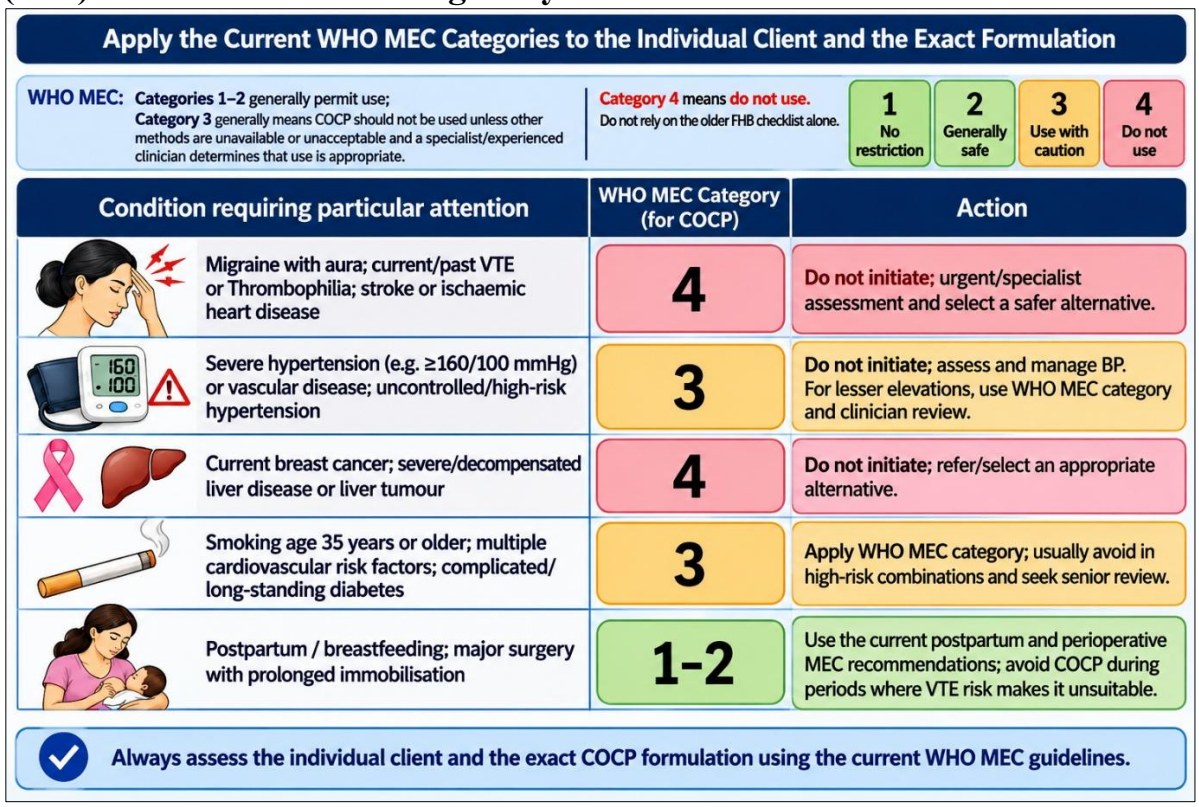
(11.1.5) Screen for migraine with aura, current/past VTE or known thrombophilia, stroke/ischaemic heart disease, significant hypertension, smoking in older clients, complicated diabetes, current breast cancer, severe/decompensated liver disease, early postpartum status and major surgery with prolonged immobilization.



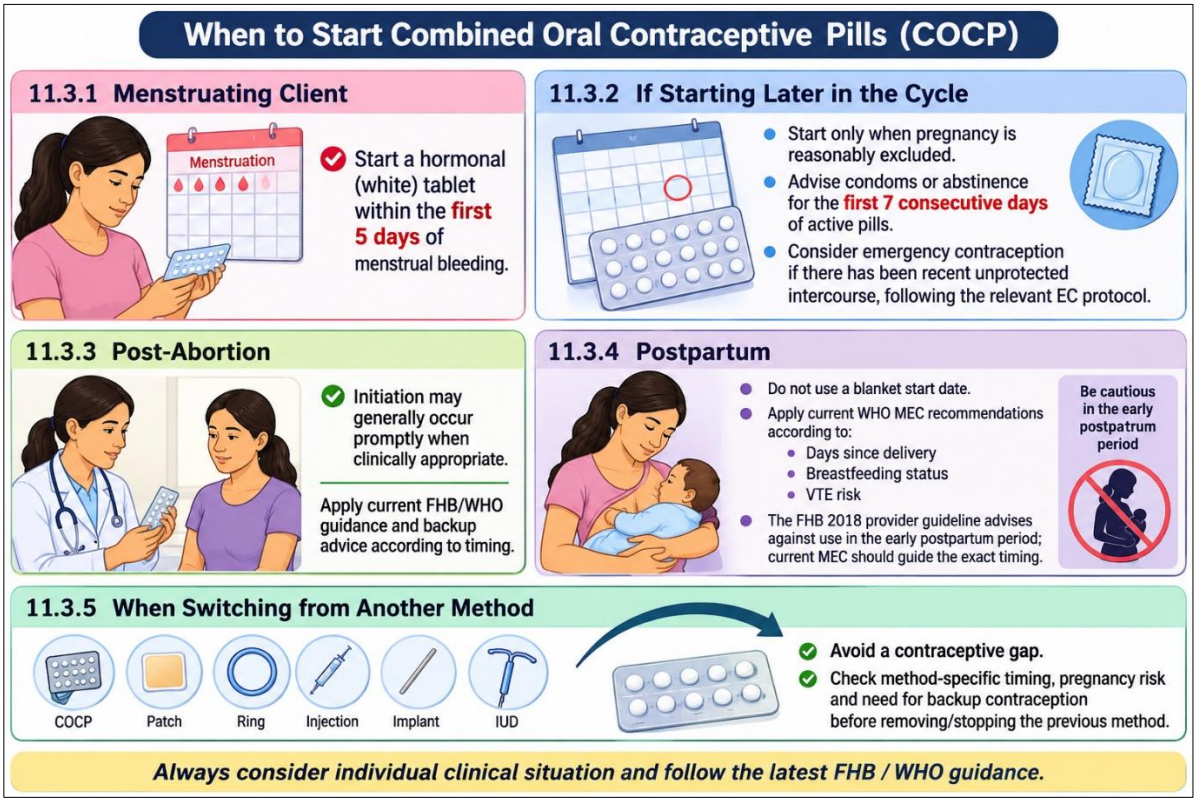
(11.1.6) Review all medicines and supplements for interactions. Enzyme-inducing medicines (for example rifampicin/rifabutin, carbamazepine, phenytoin, phenobarbital, primidone and some antiretrovirals) may reduce contraceptive effectiveness. Seek an up-to-date interaction check and recommend a suitable alternative when needed.



(11.2) Determine medical eligibility

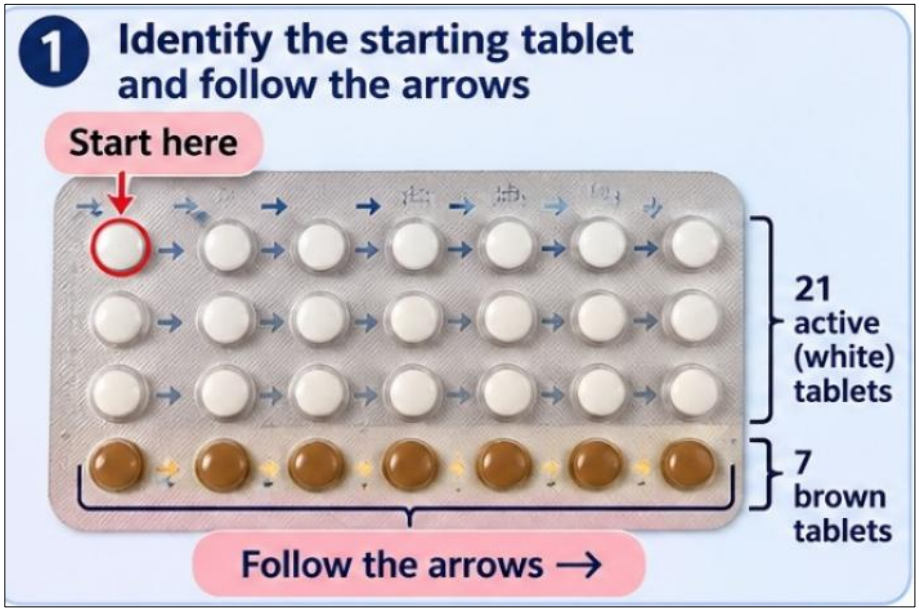


(11.3) Initiation

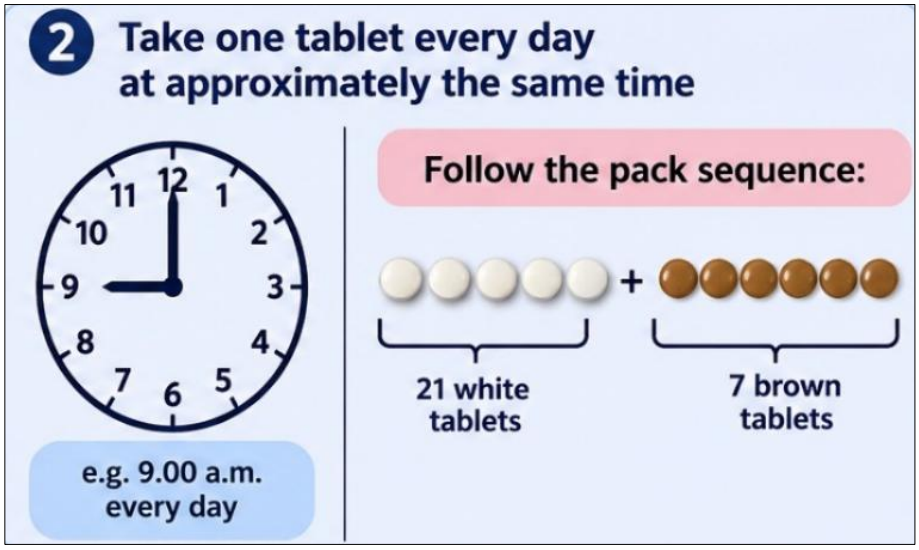


(11.4) Explain how to take the pack

(11.4.1) Show the client the actual pack, identify the starting tablet and explain the direction of arrows.



(11.4.2) Take one tablet every day at approximately the same time. Follow the pack sequence, including the 7 brown tablets where supplied.



(11.4.3) Start a new pack on the day immediately after finishing the previous pack, even if withdrawal bleeding has not occurred.



(11.4.4) Advise the client to obtain the next pack before the current pack is finished and to keep an additional pack if possible.



(11.4.5) Store in a cool, dry place away from direct sunlight and out of reach of children; follow the product label.

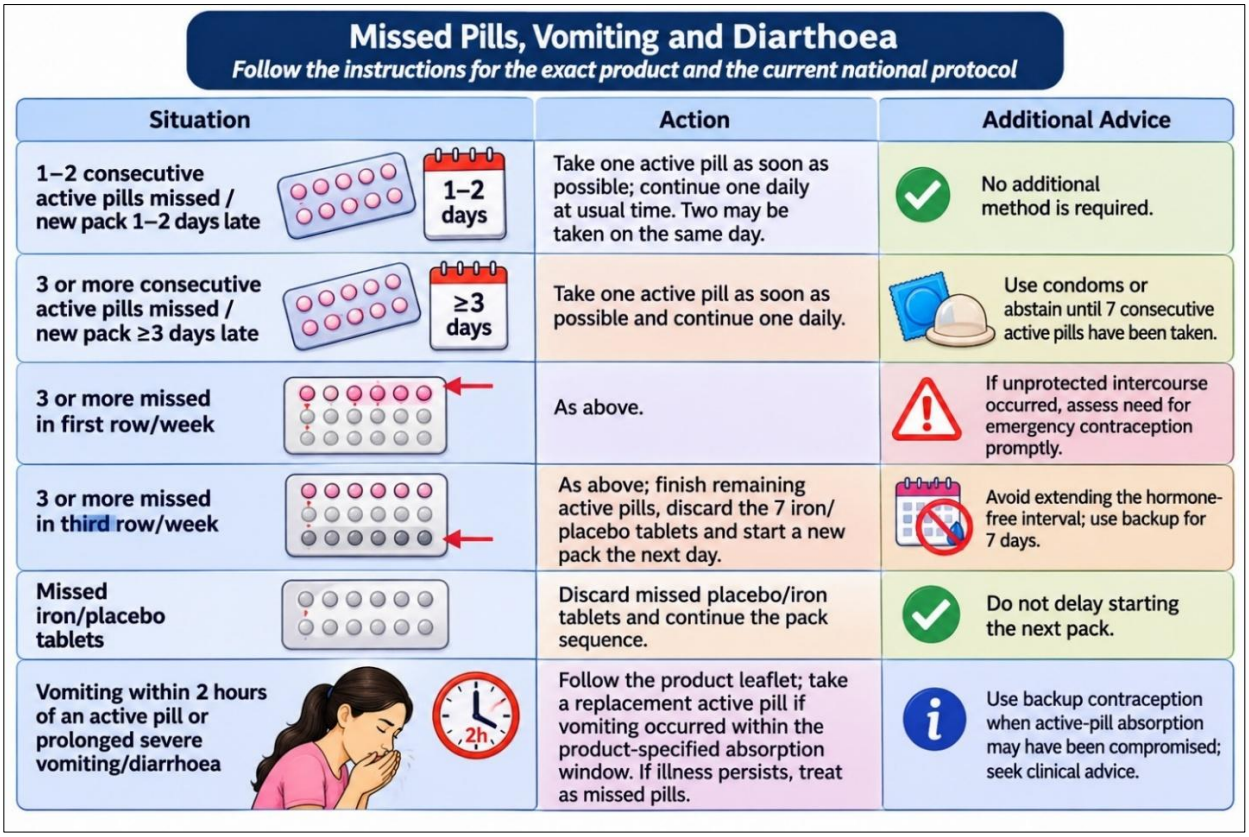


(11.5) Missed pills, Vomiting and Diarrhoea

Use the instructions for the exact product and the current national protocol. The FHB 2025 public leaflet says that if one or two days are missed, take one tablet as soon as remembered and continue the usual nightly dose; if more than two days are missed, contact the PHM/MOH or clinician. The more detailed FHB service-provider guideline (2018) gives the following practical approach for the 21 active + 7 iron-tablet pack:

Situation	Action	Additional advice
1–2 consecutive active pills missed / new pack 1–2 days late	Take one active pill as soon as possible; continue one daily at usual time. Two may be taken on the same day.	No additional method is required.
3 or more consecutive active pills missed / new pack ≥3 days late	Take one active pill as soon as possible and continue one daily.	Use condoms or abstain until 7 consecutive active pills have been taken.
3 or more missed in first row/week	As above.	If unprotected intercourse occurred, assess need for emergency contraception promptly.
3 or more missed in third row/week	As above; finish remaining active pills, discard the 7 iron/placebo tablets and start a new pack the next day.	Avoid extending the hormone-free interval; use backup for 7 days.

Missed iron/placebo tablets	Discard missed placebo/iron tablets and continue the pack sequence.	Do not delay starting the next pack.
Vomiting within 2 hours of an active pill or prolonged severe vomiting/diarrhoea	Follow the product leaflet; take a replacement active pill if vomiting occurred within the product-specified absorption window. If illness persists, manage as missed pills.	Use backup contraception when active-pill absorption may have been compromised; seek clinical advice.



(11.6) Counselling on adverse effects and warning symptoms

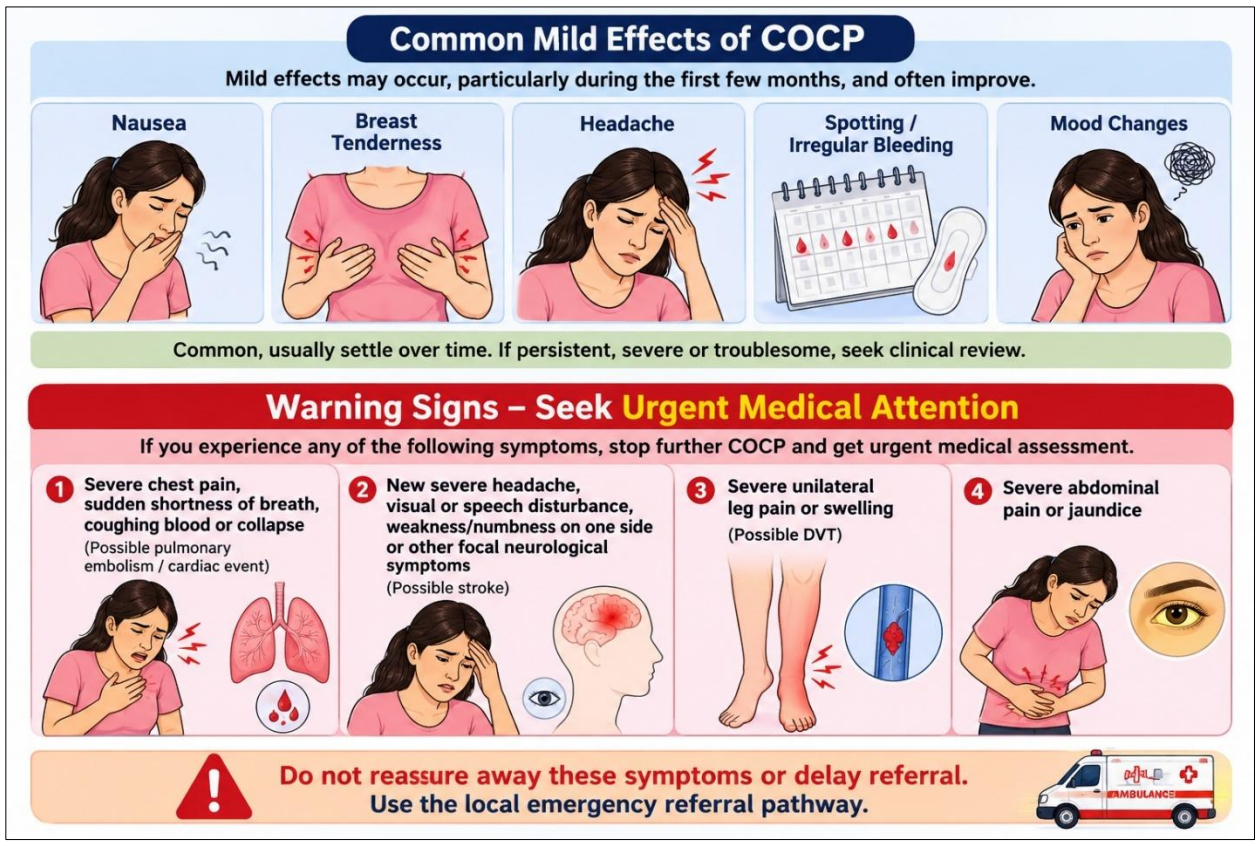
Explain that mild effects may occur, particularly during the first few months, and often improve. Common effects include nausea, breast tenderness, headache, spotting/irregular bleeding and mood changes. Persistent, severe or troublesome symptoms require clinical review.

Advise urgent medical assessment and stopping further COCP pending assessment if symptoms suggest a serious complication:

- Severe chest pain, sudden shortness of breath, coughing blood or collapse (possible pulmonary embolism / cardiac event).
- New severe headache, visual or speech disturbance, weakness/numbness on one side or other focal neurological symptoms (possible stroke).
- Severe unilateral leg pain or swelling (possible DVT).

- Severe abdominal pain or jaundice.

Do not reassure away these symptoms or delay referral. Use the local emergency referral pathway.



(11.7) Follow-up

(11.7.1) Provide a clear route to contact the PHM, MOH, family planning clinic or prescriber if questions or problems arise.

(11.7.2) At follow-up, ask about adherence, missed pills, bleeding pattern, adverse effects, satisfaction, new medical conditions and new medicines.

(11.7.3) Recheck blood pressure and reassess cardiovascular/VTE risk periodically and whenever clinically indicated; arrange at least annual clinical review in accordance with local service arrangements.

(11.7.4) Document and manage side effects; investigate persistent or new abnormal bleeding rather than assuming it is caused by the pill.

(11.7.5) Reassess eligibility if the client develops migraine, hypertension, VTE risk, starts an interacting medicine, becomes postpartum/breastfeeding or is scheduled for major surgery.

(11.8) Documentation

(11.8.1) Date, client record identifier and clinician/supervisor details.

(11.8.2) Relevant reproductive and medical history, pregnancy assessment and blood pressure.

(11.8.3) MEC eligibility assessment, contraindications/risk factors and medicine interaction review.

(11.8.4) Chosen formulation/pack, initiation date, backup advice and quantity supplied.
(11.8.5) Counselling provided, missed-pill advice, STI/condom discussion, warning symptoms and follow-up plan.
(11.8.6) Any referral, clinical decision and patient preference.

(12) Precautions

(12.1) COCP is not suitable for every client; use the current WHO MEC rather than an outdated contraindication list.
(12.2) Do not start COCP without measuring blood pressure and reviewing relevant medical history.
(12.3) Do not use COCP in pregnancy or where a WHO MEC category 4 condition is present.
(12.4) Do not assume all pill packs have the same ingredients, active/placebo arrangement or missed-pill instructions.
(12.5) Do not assume antibiotics as a class reduce COCP effectiveness; specifically check enzyme-inducing medicines and product-specific interactions.
(12.6) COCP does not protect against STIs/HIV; offer condoms and STI testing/advice when appropriate.
(12.7) Do not stop or remove an existing contraceptive method until a safe switching plan is agreed, unless urgent clinical circumstances require it.

(13) Limitations

(13.1) This SOP is an educational framework and does not replace individual clinical assessment, the latest FHB circulars, WHO MEC/SPR, product information or institutional protocols.
(13.2) The 2018 FHB provider guideline contains older eligibility thresholds and should not be used as the sole basis for prescribing; use current WHO MEC and current local policy where recommendations differ.
(13.3) Exact eligibility and missed-pill advice can vary with formulation, timing, postpartum/breastfeeding status and interacting medicines.
(13.4) Availability and composition of COCP products may change; verify the current pack and formulary.

(14) References

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